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| | | Filing Date | October 20, 2003 |
| | | First Named Inventor | Helmut D. LINK |
| | | Art Unit | 3733 |
| | | Examiner Name | David C. Comstock |
| Total Number of Pages in This Submission | 14 | Attorney Docket Number | 246472006000 |

ENCLOSURES (Check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|-------------------------|----------|--------|
| Firm Name | MORRISON & FOERSTER LLP | | |
| Signature | | | |
| Printed name | Jill DeMelle Hill | | |
| Date | September 27, 2006 | Reg. No. | 42,477 |



Docket No. 246472006000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the application of:

Helmut D. LINK

Serial No.: 10/687,933

Filing Date: October 20, 2003

For: CERVICAL INTERVERTEBRAL
PROSTHESIS SYSTEM

Examiner: David C. Comstock

Group Art Unit: 3733

COMMUNICATION RE NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

M/S Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed September 15, 2006, appellant submits a revised Section VII of its Opening Brief with this communication.

Appellant has revised Section VII of the brief to add a concise statement of each ground of rejection presented for review, and to present each argument under a separate heading for each ground of rejection on appeal. The Examiner's rejection under 35 USC 102(b) is addressed in sections VII.A and VII.B, and the Examiner's rejection under 35 USC 103(a) is addressed in sections VII.C and VII.D.

Appellant's representative discussed the Notice of Non-Compliant Appeal Brief with Patent Appeal Center Specialist Tracey Young on September 20, 2006. Specialist Young advised that the appropriate statute number and prior art reference identification should be added to subsections A through D of Argument Section VII. Further, Specialist Young instructed Appellant to re-submit only the revised Argument Section VII. In this submission, Appellant has


followed the instructions of Specialist Young in their entirety. If the Examiner should identify any remaining discrepancies, please contact the undersigned by telephone to discuss what further steps may be necessary.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, appellant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952**, referencing Docket No. **246472006000**.

Respectfully submitted,

Dated: September 27, 2006

By:



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In the application of:

Helmut D. LINK

Serial No.: 10/687,933

Filing Date: October 20, 2003

For: CERVICAL INTERVERTEBRAL
PROSTHESIS SYSTEM

Examiner: David C. Comstock

Group Art Unit: 3733

APPELLANT'S REVISED OPENING BRIEF, SECTION VII

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant re-submits Argument Section VII of its Opening Brief in response to the Notice of Non-Compliant Appeal Brief mailed September 15, 2006. Appellant's representative discussed the Notice with Patent Appeal Center Specialist Tracey Young on September 20, 2006. Specialist Young advised that the appropriate statute number and prior art reference identification should be added to subsections A through D of Argument Section VII. Further, Specialist Young instructed Appellant to re-submit only the revised Argument Section VII. In this submission, Appellant has followed the instructions of Specialist Young in their entirety. Appellant thanks Specialist Young for taking the time to discuss the Notice.

Sections I-VI, the Conclusion, and the Appendix of Appealed Claims from Appellant's Revised Opening Brief dated August 28, 2006 remain pending and unchanged by this submission.

VII. ARGUMENT

A. U.S. Patent No. 5,895,428 to Berry Does Not Anticipate Independent Method Claim 7 Under 35 USC 102(b).

In the final Action, the Examiner construed U.S Patent No. 5,895,428 to Berry (“Berry”) as disclosing an implant method and system comprising installing different prostheses 11 having sliding hinges 29, 43, referring to Figs. 2 and 12-19 and column 4, lines 11-23, of Berry. According to the Examiner, Berry discloses prostheses of differing extents, radii of curvature and effective hinge centers, ranging in size from small to large, referring to Fig. 12. The Examiner also interpreted Berry as disclosing the determination of appropriate hinge and prostheses dimensions, e.g., the hinge radius of an affected joint, by tomography and sizing and implanting the prostheses accordingly to accommodate individual anatomy, referring to col. 4, lines 19-23, of Berry.

During the prosecution leading up to this appeal, appellant explained that claim 7 is a method claim that calls for the steps of “determining the hinge radius of an affected joint” and “selecting a prosthesis with a hinge radius approximating the hinge radius of the affected joint,” neither of which steps Berry discloses. As the Board will note, the portions of Berry’s written description cited by the Examiner say not a word about the hinge radius of any of the vertebrae in question, but instead refer in very general terms to “the exact size of the implant 11.” The drawings in Berry do not show hinge radii, nor is there a word in Berry about either measuring hinge radii or of matching the prostheses chosen to the hinge radii of the vertebrae in question. Although appellant’s invention is elegant in its simplicity, Berry says nothing that puts it in possession of a person of ordinary skill in the art, who would see nothing in Berry that instructs him or her to carry out the claimed steps of measuring a hinge radius and selecting a prosthesis to fit the measured hinge radius.

The Examiner’s rebuttal to this explanation on pages 3-5 of the final Action does not suffice to support the rejection of claim 7 as anticipated. The portion of this rebuttal applicable to claim 7 reads as follows:

In response to Applicant's argument that Berry does not anticipate or render obvious Applicant's invention, * * * [w]ith respect to claim 7, it is noted that Berry does disclose the claimed method, albeit not with the same language as Applicant. It is noted that all of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. Furthermore, the embodiment which anticipates the claimed invention need not be the preferred embodiment. *In re Smith*, 32 CCPA 959, 148 F.2d 351, 65 USPQ 167; *In re Nehrenberg*, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; *In re Watanabe*, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350. Contrary to Applicant's assertion, Berry discloses a step of determining a hinge radius of an affected joint, as already set forth in the rejection. Berry states, "the exact size of the implant 11 may be formed based upon a tomographic representation of each individual's vertebrae pair, between which the implant 11 is to be placed." Berry, column 4, lines 20-23. Furthermore, as shown in Figure 12, and as acknowledged by Applicant, the size of each implant corresponds to its hinge radius and to its slide surface radius of curvature. In addition, this size or radius is determined based upon the tomograph. Thus, since size is determined by the tomograph, the radius of the joint or slide surface curvature is as well. In addition, Berry discloses selecting a prosthesis with a hinge radius approximating the hinge radius of the affected joint, i.e. the implant is sized to accommodate individual anatomy: "The invention is sized to provide as little disruption to the adjacent vertebrae for the cartilage which the joint is being replaced as is possible." *Id.* and column 9, lines 39-42.

Careful analysis of the Examiner's position reveals that neither it nor Berry answers the questions appellant has raised. The Examiner says that "Berry does disclose the claimed method, albeit not with the same language as Applicant." With all due respect to the Examiner, appellant repeats the question he asked before, what language *does* Berry use to disclose appellant's claimed method? The Examiner does not say, and for a good reason: there is no such disclosure. The disclosures in columns 4 and 9 of Berry cited by the Examiner say nothing about determining radii of curvature or hinge radii or selecting particular radii or relationships of radii. All that columns 4 and 9 of Berry talk about is determining "size," without disclosing what is meant by "size" or what criteria are employed to "size" Berry's prostheses. As appellant points out at page 4, lines 17-20, of the specification of this application, "The hinge radius is defined independently of the slide surface radius and differs from the latter in that it is measured from the center 18 of the hinge movement to the geometric midpoint of the prosthesis." That also means that mere "size" does not dictate nor is controlled by hinge radii or slide surface radii. The

language in Berry to which the Examiner *does* refer does not disclose the claimed method, either in the same or in different language.

The passages in Berry referred to by the Examiner do not recognize achieving the claimed relationship of radii at all. Instead they state that the “size” of the implant is determined based on tomography without referring to hinge radii or the radii of curvature of the hinge surfaces. “Size” refers to external dimensions of the implant and not to choosing the radii of curvature as required by the claimed method. There is no evidence that the avoiding of disruption disclosed by Berry results from or is related to the selection of hinge or sliding surface radii called for in the method of claim 7. Certainly, there is no evidence in Berry that the size of an implant is related to or controlled by the hinge radius. The specification of Berry fails to disclose in any way that the radii of curvature of the hinge surfaces 29, 43 have any correlation to the hinge radii of the involved vertebrae or disclose performing any step of selection in relation thereto. In fact, the radii of curvature of the surfaces 29, 43 shown in Berry’s figures seem to be quite a bit smaller than the hinge radii of the involved vertebrae, which shows that Berry itself does not practice the tomographic sizing of the implant asserted by the Examiner. In FIG. 9, furthermore, Berry discloses an embodiment having two articular joints in which the upper joint has its center of articulation somewhere below the prosthesis and the lower joint has its center of articulation above the prosthesis. Claim 7 does not relate to such an embodiment at all. The references in Berry to determining the size of the implant by tomography thus do not constitute disclosures or suggestions of how to choose the radii as claimed. There is no embodiment disclosed in Berry, preferred or otherwise, of the invention of claim 7 of this application.

In the response to the final Action, appellant speculated that perhaps the Examiner is saying that Berry inherently anticipates claim 7, in that practicing what Berry discloses will *necessarily and inevitably* result in performing the method of claim 7. The Examiner did not respond to that suggestion, so on this record, appellant respectfully suggests, the Board is not in a

position to affirm the rejection of claim 7 as anticipated by Berry based on inherency because the Examiner has not fairly joined issue with appellant thereon during prosecution. In any event, appellant respectfully submits that the Examiner has failed to provide a reasoned basis in fact for a finding of inherency and has thus failed to shift the burden of overcoming the rejection to appellant.

To support a rejection based on inherent disclosure in Berry, the Examiner's burden under MPEP 2112.IV. is *not* to show that practicing Berry *may* produce the claimed invention; it is the Examiner's burden to explain how following Berry's disclosure *necessarily and inevitably* produces the claimed method. The Examiner has not provided such reasoning because Berry does not support it. There is no basis in fact for reasonably believing that following Berry's disclosure will produce the method of claim 7, inherently or otherwise. For these reasons, Berry does not identically disclose the method of the invention as claimed in claim 7, and the rejection of claim 7 as anticipated by Berry should be reversed

B. U.S. Patent No. 5,895,428 to Berry Does Not Anticipate Independent System Claim 8 Under 35 USC 102(b).

System claim 8 specifically requires a set of at least two different intervertebral disk prostheses in which the prostheses closer to the head of the subject into which they are to be implanted ("in a cranial direction" in the words of claim 8) have hinge radii that are greater than the hinge radii of the prostheses that are relatively toward the base of the spine ("in a direction more caudal" in the words of claim 8). U.S. Patent No. 5,895,428 to Berry ("Berry") discloses the opposite of what appellant claims, as can be seen from Berry's Fig. 12 and the supporting disclosure. Fig. 12 unmistakably shows the radii of curvature of the hinge surfaces increasing as one proceeds down the spine in the caudal direction. This increase in radii, contrary to the claimed invention, is also illustrated at col. 8, line 18 – col. 9, line 8, of Berry: In the C1-C3 section R2, the hinge radius of curvature, is 0.188 inches, in the C4-C7 section R2 is 0.219 inches and in the L1-L5 section, R2 is 0.4375 inches. Furthermore, Berry does not correlate hinge radii or radii of curvature to the overall dimensions of the implants.

The portion of the Examiner's rebuttal in the final Action corresponding to claim 8 reads as follows:

In response to Applicant's argument that Berry does not anticipate or render obvious Applicant's invention, and with respect to claim 8, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. * * *. Here, claim 8, essentially requires only that one of two prostheses have a greater slide surface radius of curvature than the other and that the former is *capable of being selected* to replace an intervertebral disk lying in a more cranial direction than the other. Berry clearly discloses at least two prostheses wherein one has a greater slide surface radius of curvature than another. Furthermore, if it were so desired, there is nothing to preclude one having a greater radius from being selected to replace an intervertebral disk lying in a more cranial direction. [Emphasis in original.]

The Examiner argues that claim 8 sets forth statements of intended use that do not define structure different from what Berry discloses. The Examiner seems to think that all claim 8 defines is two prostheses of different sizes. That is not so. The claimed system includes at least two different prostheses, it is true, but they differ in characteristics that do not flow from size *per se* but exist independently of mere size, the hinge radii and radii of curvature of the slide surfaces. The invention of claim 8 is a set of prostheses having a defined relationship and order to one another that Berry does not teach or suggest. In particular, there is no support for the Examiner's statement that "if it were so desired, there is nothing [in Berry] to preclude one having a greater radius from being selected to replace an intervertebral disk lying in a more cranial direction." Berry teaches exactly the opposite.

The Examiner's position may be characterized as saying, "The invention of claim 8 is nothing more than a pair of prostheses having different slide radii, which Berry shows." However, claim 8 is directed to a system in which the prostheses are arranged in a specified manner so that they may be used by the physician to perform cervical intervertebral disk replacement surgery in a way that Berry not only fails to disclose, it teaches away from. The Board should note that the prostheses of this invention and of Berry are not reversible in how

they can be implanted. That is, these prostheses have top and bottom aspects and cannot be implanted “upside down.” When prostheses are arranged as claimed by appellant in claim 8, their surfaces are oriented relative to each other in a manner that is opposite of what Berry would suggest even if read as the Examiner proposes. Furthermore, the prostheses making up appellant’s claimed prosthesis system are different in structural respects that Berry does not disclose, either expressly or inherently. As a result, Berry not only fails to disclose the invention of claim 8 identically, it implicitly teaches away from it. The rejection of claim 8 as anticipated by Berry should be reversed.

C. **U.S. Patent No. 5,895,428 to Berry, By Itself, Does Not Show That the Subject Matter of Method Claims 12-15, as a Whole, Would Have Been Obvious Under 35 USC 103(a) at the Time the Invention Was Made.**

Method claims 12-15 stand rejected as obvious over U.S. Patent No. 5,895,428 to Berry (“Berry”). Starting from his belief that Berry anticipates claim 7, the Examiner asserts that it would have been obvious to choose the dimensions claimed in claims 12-14 “since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e., sliding joint prostheses of different sizes, discovering the optimum or workable ranges of the same involves only routine skill in the art.”

This rejection suffers from three crucial defects. First, it relies on the disclosures in Berry that allegedly support the anticipation rejection of base method claim 7, which appellant has already shown Berry does not provide, either expressly or inherently. To the extent that the Examiner relies on inherent disclosure to reject claim 7 as anticipated, furthermore, the rejection is untenable because, as aptly stated in MPEP 2141.02, at page 2100-132, “Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.” For these reasons alone, the rejection of claims 12-14, which depend directly or indirectly from claim 7, on Berry alone should be reversed.

Second, the rejection does not adequately deal with claim 14 or independent claim 15, the latter of which was not rejected as anticipated by Berry. The Examiner's full statement on page 3 of the final Action of the rejection of claim 15 (along with claims 4, 5 and 11-14) was as follows:

Berry discloses the claimed invention except for explicitly disclosing providing slide surface radii of below 15 mm or 18 mm for a prosthesis and over 18 mm for another prosthesis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device with a slide surface radii below 15 mm or 18 mm for one prosthesis and over 18 mm for another prosthesis, or with any of numerous slide surface radii, since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e. sliding joint prostheses of different sizes, discovering the optimum or workable ranges of the same involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 15, as the Board will note from the appendix of claims on appeal, is quite different from claim 8 and certainly does not differ from claim 8 only in reciting dimensions as asserted by the Examiner. Claim 14 does not recite numerical dimensions *per se*, but instead requires performance of the method of claim 7 so as to select the first prosthesis to be implanted in the more cranial position to have a smaller anterior-posterior extent and larger slide surface radius than the second prosthesis, which is implanted at a position farther from the head of the patient. The Examiner has not cited prior art which deals with the subject matter of the invention of claim 14 or 15 as a whole and certainly has not made the findings necessary to support an obviousness rejection of claims 14 and 15 on Berry. The rejection of claims 14 and 15 may be reversed on this ground alone.

Third, the basic rationale underlying the rejection assumes what the "general conditions" of the claims are, contrary to the requirement that the subject matter of the claimed invention *as a whole* must be evaluated for obviousness over the prior art. In this case, one of the key features of the method of the invention of claims 12 and 13 which Berry does not even hint at is the need to measure the hinge radii of the affected vertebrae so that the person of ordinary skill in the art would have been may choose the claimed slide surface radii for the different prostheses

used in the claimed method. There is nothing in Berry which suggests in any way either that the slide surface radii of the vertebrae are related to the selection of the prostheses or that, based on such a selection, the slide surface radii should relate to the location along the spine as claimed.

Appellant also notes that Berry says nothing that would suggest that selecting any particular slide surface radii, let alone slide radii of greater and less than 15 or 18 mm, has any relationship to the performance of the prosthesis system. Thus, the case law cited by the Examiner is inapposite because there is no evidence of record that suggests persons of ordinary skill in the art would have considered varying slide surface radii to be result-effective, let alone choosing the particular radius relationships claimed by appellant. *See, e.g., In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As a result, it is incorrect to reject claims 12 and 13, or the other claims relating to specific radii, claims 4 and 5, on the ground that “discovering the optimum or workable ranges of [the general conditions of the prior art] involves only routine skill in the art.”

For all of these reasons, the rejection of claims 12-15 as obvious over Berry alone should be reversed.

D. U.S. Patent No. 5,895,428 to Berry, By Itself, Does Not Show That the Subject Matter of System Claims 4, 5 and 11, as a Whole, Would Have Been Obvious Under 35 USC 103(a) at the Time the Invention Was Made.

Since U.S Patent No. 5,895,428 to Berry (“Berry”) does not provide the disclosure against base claim 8 that the Examiner says it does, the obviousness rejection of these claims on Berry alone cannot stand.

However, even if the Board were to assume that claim 8 was properly rejected as anticipated by Berry, which it was not as explained above, appellant respectfully points out that the same rationale presented above with respect to method claims 12-15 applies to system claims

4, 5 and 11 as well.¹ Berry says nothing that would suggest that selecting any particular slide surface radii, let alone slide radii of greater and less than 18 mm, would have had any relationship to the performance of the prosthesis system, so it could not have been obvious from Berry by itself to have modified the prosthesis system of claim 8 to arrive at the subject matter of system claims 4, 5 and 11. Thus, it was incorrect of the Examiner to reject claims 4 and 5 on the ground that “discovering the optimum or workable ranges of [the general conditions of the prior art] involves only routine skill in the art.” In this record, there is no evidence at all that persons of ordinary skill in the art would have had any reason to choose or optimize radii of slide surface curvature as claimed.

Claim 11 is analogous to method claim 15, and the Examiner failed to make out a *prima facie* case of obviousness of claim 11 for the same reasons as he failed to do so for claim 15. Berry alone does not provide the necessary evidence of motivation to make the invention of claim 11.

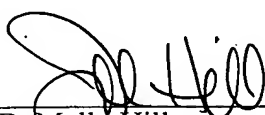
¹ By saying this, however, appellant is not conceding that claims 12-15 rise or fall with claims 4, 5 and 11. Base claims 7 and 8 are different, and the differences between the base claims and their dependent claims are likewise different, as argued above.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, appellant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. **246472006000**.

Respectfully submitted,

Dated: September 27, 2006

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